UNITED STATES DISTRICT COURT FOR THE DISTRICT OF PUERTO RICO

GERARDO CAMPOS, ET AL.,

Plaintiffs, : CASE NO. 3:12-cv-01529-PAD

:

v.

SAFETY-KLEEN SYSTEMS, INC., ET AL.,

Defendants. :

DEFENDANT SAFETY-KLEEN SYSTEMS, INC.'S OPPOSING STATEMENT OF MATERIAL FACTS IN SUPPORT OF ITS OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGEMENT/MOTION TO STRIKE DR. PETER SHIELDS UNDER FEDERAL RULE OF EVIDENCE 702 AND DAUBERT

DEFENDANT SAFETY-KLEEN SYSTEMS, INC. ("Safety-Kleen"), by and through its undersigned counsel, and pursuant to Local Rules 56(c) and (e), respectfully submits this Opposing Statement of Material Facts in Support of its Opposition to Plaintiffs' Motion for Summary Judgment/Motion to Strike Dr. Peter Shields Under Federal Rule of Evidence 702 and *Daubert*:

1. Plaintiffs' Statement No. 1: SK-105 contains benzene.

Qualified denial: Safety-Kleen 105 Virgin Solvent (SK 105) was made up of refined petroleum distillates referred to as mineral spirits. The primary chemical exposure in the product was mineral spirits, not benzene. Mineral spirits, also known as Stoddard solvents, are a complex mixture of hydrocarbons that mainly consist of C9-CI2 hydrocarbons (>80% aliphatic) that have a boiling range of 150-200 degrees C. Benzene is present as a trace impurity or residual component of mixed petroleum products like the Virgin 105 mineral spirits because it is a naturally occurring compound in crude oil and natural gas. Thus, some very low concentration of benzene remains in products refined from these sources because of the nature of the fractional

distillation and hydrotreating process. According to an analysis conducted by Safety-Kleen from 1991 to 1993 for the benzene content in the virgin 105 solvent, which included over 1,400 samples provided by suppliers, the average benzene concentration of the virgin solvent was 19.9 mg/L or 22.6 ppm on a volume basis. Notably, the average benzene content for the virgin solvent provided by Exxon, the predominate supplier referenced in the Safety-Kleen Puerto Rican supplier data, was reported to be 9.5 mg/L or 10.8 ppm in 1993 and in 2013 was reported to be < 0.4 ppm. Additionally, Puerto Rico supplier records indicate the provision of Rule 66 mineral spirits during a portion of the relevant time period, and the 1993 data found an average of 7.4 mg/L benzene in the Rule 66 virgin mineral spirits tested. (Report of John Spencer, pg. 5-7, Exhibit E; Report of Julie Panko, pg. 13, Exhibit F; Report Dr. David Pyatt, pg. 6, Exhibit G).

2. <u>Plaintiffs' Statement No. 2:</u> Benzene exposure causes chronic myeloid leukemia (hereinafter "CML").

Deny: The available scientific evidence does not support a conclusion that benzene causes CML under any circumstances. Plaintiffs' own expert Dr. David Goldsmith admitted this hypothesis does not have general support within the scientific community. The International Agency for Research on Cancer, an organization that Plaintiffs' own experts identify as a reliable authority on evaluation of the etiology of cancer, found there is insufficient evidence that exposure to benzene causes CML. Safety-Kleen's experts, Dr. David Pyatt, Dr. David Garabrant, and Dr. Peter Shields have reviewed all relevant and reliable literature on this issue, and have concluded there is insufficient evidence that there is an increased risk of CML for persons exposed to benzene, at any level. Plaintiffs' experts acknowledge that the International Agency for Research on Cancer ("IARC") is a reliable authority when it comes to evaluating

carcinogens. And IARC has determined there is insufficient evidence that benzene exposures can cause CML.

This is the subject of Defendant Safety-Kleen's Motion for Summary Judgment (ECF No. 113), Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of David F. Goldsmith, Ph.D. and related Reply brief (ECF Nos. 93 and 123), Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of Dr. Arthur Frank and related Reply brief (ECF Nos. 95 and 125), and Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of Melvyn Kopstein, Ph.D. and related Reply brief (ECF Nos. 97 and 124), the arguments and authorities in which are incorporated here by reference as though laid out in full. (Report of Dr. Peter Shields, pg. 32, ¶ 6, Exhibit B; Declaration of Dr. Peter Shields, July 15, 2014, Exhibit A; Report of Dr. David Garabrant, M.D., pg. 8-13, ¶¶ 6-13, Exhibit H; Report of Dr. David Pyatt, pg. 2, 6-9, Exhibit G; Deposition of David Goldsmith, 82:23-83:2, 83:6-84:7, Exhibit D; WHO, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 100F-Benzene (2012 Monograph), at 259, section 2.1.3, Exhibit I).

3. <u>Plaintiffs' Statement No. 3:</u> Plaintiff, Gerardo Campos, was exposed to SK-105.

Qualified denial: The only evidence that Plaintiff Gerardo Campos used Safety-Kleen 105 Solvent is his own testimony in this case. There are no other witnesses or any other documentary evidence that establish Plaintiff used SK 105. Safety-Kleen admits that it has records of SK 105 service to Makita USA, Inc. from January 1996 through October 2004. Safety-Kleen denies Mr. Campos was exposed to SK 105 at National Rental. Plaintiffs' expert Dr. Melvyn Kopstein withdrew exposure calculations relevant to National Rental, given that the parts washer was reportedly located outdoors, and those conditions would be inconsistent with the air measurements that his method incorporates. Safety-Kleen denies that it provided SK 105

to Tool Box, Inc. (Kopstein Dep. at 174:16-175:12; Safety-Kleen's Objections and Answers to Plaintiffs' First Set of Interrogatories, Request No.4, attached in pertinent part at Exhibit J)

- 4. <u>Plaintiffs' Statement No. 4:</u> Plaintiff, Gerardo Campos, developed CML. Admit.
- 5. <u>Plaintiffs' Statement No. 5:</u> Plaintiff, Gerardo Campos', CML is causally related to his exposure to benzene through his use of SK-105.

Deny. The majority of CML cases are idiopathic or have no known cause. There is no basis for a claim that Mr. Campos' exposure to SK 105 caused, contributed to, or played a role in the causation of his CML. Benzene is ubiquitous. It is found in the ambient air, in gasoline and diesel exhaust, and in many household products. Despite this, Plaintiffs' experts do not compare Mr. Campos exposures to any other occupational, non-occupational, or background benzene exposures he may have had. Plaintiffs' experts d not compare his calculated exposures to any epidemiological literature. If benzene is capable of causing CML, and if it did, in fact, cause Campos' CML, Plaintiffs' experts did not and cannot reliably rule out other potential sources of benzene exposure, such as background benzene exposure from the ambient air, or Campos' extensive smoking history. Dr. Arthur Frank even goes so far as to admit that "it's purely speculative" whether or not Campos would have developed CML if he never worked with Safety-Kleen or smoked.

Safety-Kleen's experts, Dr. David Pyatt, Dr. David Garabrant, and Dr. Peter Shields have reviewed all relevant and reliable literature on this issue, and have concluded there is insufficient evidence that there is an increased risk of CML for persons exposed to benzene, at any level. This is the subject of Defendant Safety-Kleen's Motion for Summary Judgment (ECF No. 113),

Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of David F. Goldsmith, Ph.D. and related Reply brief (ECF Nos. 93 and 123), Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of Dr. Arthur Frank and related Reply brief (ECF Nos. 95 and 125), and Safety-Kleen's Motion to Exclude the Testimony, Opinions and Report of Melvyn Kopstein, Ph.D. and related Reply brief (ECF Nos. 97 and 124), the arguments and authorities in which are incorporated here by reference as though laid out in full. (Report of Dr. David Garabrant, M.D., pg. 13, ¶ 16, Exhibit H; Report of Dr. Peter Shields, pg. 12, and pg. 32, ¶ 10, Exhibit B; Report of Dr. David Pyatt, pg. 9, Exhibit G; Frank Dep., at 17:14-18 (did not review or ask for Plaintiff's deposition), 78:8-79:9 (does not care about benzene content of SK 105), 83:24-85:8 (did not review Kopstein's report before forming his causation opinions and does not rely on any dose), 162:5-23, 164:14-22), Exhibit K.

As allowed by Local Rule 56(c), Safety-Kleen asserts the following Material Facts in Support of its Opposition to Plaintiff's Motion for Summary Judgment:

- SK 1. Safety-Kleen 105 is a parts-washing solvent comprised of a refined petroleum distillate, commonly referred to as mineral spirits, which Safety-Kleen historically acquired from major petroleum refiners. (Report of John Spencer, pg. 5, Exhibit E; Deposition of Goldsmith, 78:3-13, Exhibit D; Deposition of Kopstein, 13:23-14:4, Exhibit L; Deposition of Frank, 78:8-18 (relying on the testimony of Plaintiffs' other experts to assess the chemical mixture of Safety-Kleen 105 Solvent), Exhibit K)
- SK 2. No industry or governmental organization has identified mineral spirits, such as SK 105, as a carcinogen. (Report of John Spencer, pg. 5-7, Exhibit E; Report of Dr. David Pyatt, pg. 7, Exhibit G)

- SK 3. Mineral spirits are not benzene. Like all refined petroleum distillates, benzene may appear in mineral spirits as a naturally-occurring, trace contaminant. (Report of John Spencer, pg. 6, Exhibit E; Report of Julie Panko, pg. 13, Exhibit F; Report of Dr. David Pyatt, pg. 4, Exhibit G; Report of Peter Shields, M.D., pg. 25, 26, 31 ¶ 5, Exhibit C).
- SK 4. Mineral spirits do not have the same toxic effect as benzene. Even high dose, chronic exposure to mineral spirits is not toxic to the bone marrow or hematopoietic system of humans or animals. (Report of Dr. David Pyatt, pg. 7, Exhibit G; Report of Peter Shields, M.D., pg. 25, Exhibit B).
- SK 5. Exposure to mineral spirits, like SK 105, does not cause CML. (Report of David Garabrant, M.D., pg. 13, ¶ 15, Exhibit H; Report of Peter Shields, M.D., pg. 25, Exhibit B; Report of David Pyatt, Ph.D., pg. 2, Exhibit G).
- SK 6. Plaintiffs' experts did not review studies evaluating the ability of mineral spirits to cause CML. (Deposition of Goldsmith, 98:3-12, 175:3-177:10, Exhibit D; Deposition of Frank, 46:17-47:7, Exhibit K).
- SK 7. There is insufficient evidence that exposure to benzene causes CML. (Report of David Garabrant, M.D., pg. 13, ¶ 15, Exhibit H; Report of Peter Shields, M.D., pg. 25, Exhibit B; Report of David Pyatt, Ph.D., pg. 2, Exhibit G; WHO, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 100F-Benzene (2012 Monograph), at 259, section 2.1.3, Exhibit I).
- SK 8. The majority of cases of CML are idiopathic or have no known cause. (**Report of Dr. Peter Shields, pg. 12, Exhibit B; Report of Dr. David Pyatt, pg. 9, Exhibit G**).

- SK 9. The International Agency for Research on Cancer ("IARC") is a reliable authority in evaluating human carcinogens. (Deposition of Goldsmith, 117:3-12, Exhibit D; Deposition of Frank, 97:24-98:3, 99:6-12, Exhibit K).
- SK 10. IARC concluded there is insufficient evidence to support a conclusion that benzene exposure causes CML. (Deposition of Goldsmith, 122:1-20, Exhibit D; WHO, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 100F-Benzene (2012 Monograph), at 259, section 2.1.3, Exhibit I).
- SK 11. Safety-Kleen designated three experts to discuss the issue of general and specific causation: Dr. Peter Shields, Dr. David Garabrant, and Dr. David Pyatt. Plaintiffs have not challenged the testimony or opinions of Dr. Garabrant and Dr. Pyatt. (Report of David Garabrant, M.D., Exhibit H; Report of Peter Shields, M.D., Exhibit B; Report of David Pyatt, Ph.D., Exhibit G).

Respectfully submitted,

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ATTORNEYS FOR DEFENDANT SAFETY-KLEEN SYSTEMS, INC.

CERTIFICATE OF SERVICE

On June 13, 2014, I electronically submitted the foregoing document with the clerk of the court for the U.S. District Court, District of Puerto Rico, using the ECF system. I hereby certify that I have served all counsel and/or *pro se* parties of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

By: /s/ Amanda M. Koch
Amanda M. Koch